TIME SENSITIVE PATENT INFORMATION PURSUANT TO 21 C.F.R. 314.53 (c) FOR NDA # 20-553

The following is provided in accordance with the Drug Price Competition and Patent Term Restoration Act of 1984:

Trade Name:	OxyContin®
Active Ingredient(s):	Oxycodone Hydrochloride
Strength(s):	10, 20, 40, 80 and 160 mg
Dosage Form:	Extended-Release Tablets
Approval Date:	10 mg. – December 12, 1995 20 mg. – December 12, 1995 40 mg. – December 12, 1995 80 mg. – January 6, 1997 160 mg. – March 15, 2000
Applicant:	Purdue Pharma L.P. One Stamford Forum Stamford, CT 06901-3431
Listed Drug:	OxyContin® (Oxycodone Hydrocloride) Controlled-Release Tablets
Indication(s):	OxyContin® (Oxycodone Hydrocloride) Controlled-Release Tablets are indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

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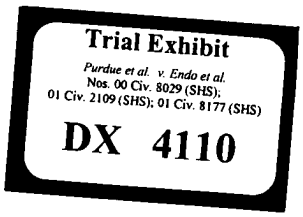

P 650650

1. **United States Patent No. 4,861,598**

A. This information should be provided for each individual patent submitted:

U.S. Patent Number: 4,861,598

Expiration Date: August 29, 2006

Type of Patent (*indicate all that apply*):

Drug Substance (Active Ingredient)	____ Y	_x_ N
Drug Product (Composition/Formulation)	_x_ Y	____ N
Method of Use	____ Y	_x_ N

a. If patent claims method(s) of use, please specify approved method(s) of use or method(s) of use for which approval is being sought that are covered by patent:
N/A

Name of Patent Owner: Euro-Celtique S.A.

U.S. Agent (*if patent owner or applicant does not reside or have place of business in the U.S.*):
Philip C. Strassburger, Purdue Pharma L.P., 1 Stamford Forum, Stamford, CT 06901-3431

B. The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.

The undersigned declares that the above stated United States Number 4,861,598 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:

_x_ currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.

OR

___ the subject of this application for which approval is being sought.

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P 650651

2. **United States Patent No. 4,970,075**

A. This information should be provided for each individual patent submitted:

U.S. Patent Number: 4,970,075

Expiration Date: August 29, 2006

Type of Patent (*indicate all that apply*):

Drug Substance (Active Ingredient)	____ Y	_x_ N
Drug Product (Composition/Formulation)	_x_ Y	____ N
Method of Use	____ Y	_x_ N

a. If patent claims method(s) of use, please specify approved method(s) of use or method(s) of use for which approval is being sought that are covered by patent:
N/A.

Name of Patent Owner: Euro-Celtique S.A.

U.S. Agent (*if patent owner or applicant does not reside or have place of business in the U.S.*):
Philip C. Strassburger, Purdue Pharma L.P., 1 Stamford Forum, Stamford, CT 06901-3431

B. The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.

The undersigned declares that the above stated United States Number 4,970,075 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:

_x_ currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.

OR

___ the subject of this application for which approval is being sought.

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3. **United States Patent No. 5,266,331**

A. This information should be provided for each individual patent submitted:

U.S. Patent Number: 5,266,331

Expiration Date: October 26, 2007

Type of Patent (*indicate all that apply*):

Drug Substance (Active Ingredient)	____ Y	_x_ N
Drug Product (Composition/Formulation)	_x_ Y	____ N
Method of Use	____ Y	_x_ N

a. If patent claims method(s) of use, please specify approved method(s) of use or method(s) of use for which approval is being sought that are covered by patent:
N/A

Name of Patent Owner: Purdue Pharma L.P.
The Purdue Frederick Company
The P.F. Laboratories, Inc.
The Purdue Pharma Company

U.S. Agent (*if patent owner or applicant does not reside or have place of business in the U.S.*):
Philip C. Strassburger, Purdue Pharma L.P., 1 Stamford Forum, Stamford, CT 06901-3431

B The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.

The undersigned declares that the above stated United States Number 5,266,331 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:

_x_ currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.

OR

___ the subject of this application for which approval is being sought.

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4. **United States Patent No. 5,508,042**

A. This information should be provided for each individual patent submitted:

U.S. Patent Number: 5,508,042

Expiration Date: April 16, 2013

Type of Patent (*indicate all that apply*):

Drug Substance (Active Ingredient)	____ Y	_X_ N
Drug Product (Composition/Formulation)	____ Y	_X_ N
Method of Use	_X_ Y	____ N

a. If patent claims method(s) of use, please specify approved method(s) of use or method(s) of use for which approval is being sought that are covered by patent: Management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

Name of Patent Owner: Purdue Pharma L.P.
The Purdue Frederick Company
The P.F. Laboratories, Inc.
The Purdue Pharma Company

U.S. Agent (*if patent owner or applicant does not reside or have place of business in the U.S.*): Philip C. Strassburger, Purdue Pharma L.P., 1 Stamford Forum, Stamford, CT 06901-3431

B. The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.

The undersigned declares that the above stated United States Number 5,508,042 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:

_X_ currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.

OR

___ the subject of this application for which approval is being sought.

5. **United States Patent No. 5,549,912**

A. This information should be provided for each individual patent submitted:

U.S. Patent Number: 5,549,912

Expiration Date: October 26, 2007

Type of Patent (*indicate all that apply*):

Drug Substance (Active Ingredient)	___ Y	_x_ N
Drug Product (Composition/Formulation)	_x_ Y	___ N
Method of Use	___ Y	_x_ N

a. If patent claims method(s) of use, please specify approved method(s) of use or method(s) of use for which approval is being sought that are covered by patent:
N/A.

Name of Patent Owner: Purdue Pharma L.P.
The Purdue Frederick Company
The P.F. Laboratories, Inc.
The Purdue Pharma Company

U.S. Agent (*if patent owner or applicant does not reside or have place of business in the U.S.*):
Philip C. Strassburger, Purdue Pharma L.P., 1 Stamford Forum, Stamford, CT 06901-3431

B. The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.

The undersigned declares that the above stated United States Number 5,549,912 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:

_x_ currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.

OR

___ the subject of this application for which approval is being sought.

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Purdue v. Endo

6. **United States Patent No. 5,656,295**

A. This information should be provided for each individual patent submitted:

U.S. Patent Number: 5,656,295

Expiration Date: October 26, 2007

Type of Patent (*indicate all that apply*):

Drug Substance (Active Ingredient)	___ Y	_X_ N
Drug Product (Composition/Formulation)	_X_ Y	___ N
Method of Use	_X_ Y	___ N

a. If patent claims method(s) of use, please specify approved method(s) of use or method(s) of use for which approval is being sought that are covered by patent: Management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

Name of Patent Owner: Purdue Pharma L.P.
The Purdue Frederick Company
The P.F. Laboratories, Inc.
The Purdue Pharma Company

U.S. Agent (*if patent owner or applicant does not reside or have place of business in the U.S.*):
Philip C. Strassburger, Purdue Pharma L.P., 1 Stamford Forum, Stamford, CT 06901-3431

B. The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.

The undersigned declares that the above stated United States Number 5,656,295 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:

_X_ currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.

OR

___ the subject of this application for which approval is being sought.

Signed: _____
Philip C. Strassburger
U.S. Patent and Trademark Office Registration No. 34,258

Date: March 28, 2002

Title: Vice President, Intellectual Property Counsel
Purdue Pharma L.P.

Telephone Number: (203) 588-7639

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